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EXAMINER

LANG, AMY T

ART UNIT	PAPER NUMBER
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3731

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10/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/753,848	Applicant(s) TRABADA ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-13, 22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13, 22, 24, and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-5, 7, 10-12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) in view of Cohen et al. (US 5,167,239) and Ackerman et al. (US 6,802,825 B2).

With regard to claim 1, Richter discloses a guidewire (2) which, when in an operative position, extends through a body lumen to a desired location and therefore overlaps the instantly claimed guide track ([0010]). Catheter (15) comprises a modular device disposed over and therefore coupled to the guidewire ([0018]). The catheter can be removed from the guidewire so that it is selectively coupled to the guidewire. Richter further teaches that the catheter comprises a drive mechanism (1) that engages the

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guidewire to move the catheter along the guidewire ([0019]). The drive mechanism "crawls" along the guidewire to move the catheter along the guidewire ([0016]; [0019]).

However, Ritcher does not specifically disclose the guidewire comprising an anchoring module. Cohen et al. (hereinafter Cohen) discloses a guidewire with a distal anchoring balloon (Figure 1). A balloon (14) located on the distal end of the balloon is inflated to anchor and secure the guidewire at the desired location within a patient's lumen (column 3, lines 29-36).

However, Cohen does not specifically disclose the balloon as moveable on the guidewire. Ackerman et al. (hereinafter Ackerman) discloses a balloon that is also expanded to anchor and secure a catheter in place within a lumen ([column 4, lines 44-48]). Sleeve (12) is slid distally to expand and displace the balloon. Specifically, the sleeve is slid forward and over the proximal end of the balloon. This causes the fluid within the balloon to be displaced forward, toward the distal end (column 5, lines 35-44). Displacing the fluid also causes the balloon, or at least a portion of the balloon, to be slid forward as well. For instance, when a partially expanded balloon is compressed, the balloon surface is redistributed along with the fluid inside the balloon. The balloon has been moved to the desired location where the balloon is expanded to the size of a patient's lumen. Since the sleeve causes the balloon to become displaced, the sleeve clearly overlaps the instantly claimed anchoring drive mechanism.

Ritcher does not specifically disclose an anchoring mechanism on the guidewire. Cohen discloses a guidewire that advantageously comprises an anchoring balloon to secure the guidewire during catheter procedures. Ackerman teaches that it is known in

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the art to utilize an outer sleeve/drive mechanism to displace the balloon for expansion. The outer sleeve/drive mechanism would move along the guidewire and therefore be engaged with the guidewire. Therefore, it would have been obvious at the time of the invention for the guidewire of Ritcher to comprise the anchoring balloon of Cohen that is moveably displaced as taught by Ackerman.

With regard to claim 2, the guide track (2) of Ritcher is specifically disclosed as a guidewire.

With regard to claim 3, as shown in Figures 1 and 2 of Ritcher, the guidewire comprises a substantially helical surface. Additionally, Cohen teaches that helically coiled wires are well known in the art (column 1, lines 19-23).

With regard to claim 4, the drive mechanism (1) of the catheter (15) is specifically disclosed as a motor ([0015]).

With regard to claim 5, Ritcher discloses the drive mechanism as a miniature oscillating motor, which an electric motor encompasses (see paragraph [0001] of Strobl (US 2004/0183383 A1)).

With regard to claim 7, Ritcher further discloses the catheter as comprising a guide track receiving lumen (18) ([0018]).

With regard to claims 10 and 11, the balloon of Cohen is the extendible member and component 26 of Cohen overlaps the inflation lumen.

With regard to claim 12, catheter (15) of Ritcher, the modular device, also comprises a balloon (19) located on the exterior of the device (Figure 7). The balloon is expanded to deploy the stent, but is also capable of anchoring the modular device

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within a patient's lumen ([0019]). Therefore, balloon (19) overlaps the instantly claimed second extendible member.

With regard to claim 13, it is the examiner's position that the balloon (19) on the exterior of the catheter intrinsically comprises an inflation lumen. This is well known in the art to expand a balloon.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) in view of Cohen (US 5,167,239) and Ackerman (US 6,802,825 B2) as applied to claim 1 above, and further in view of Kindlein (US 7,229,401 B2) or Ziegler et al. (US 6,971,990 B2).

Ritcher in view of Cohen and Ackerman disclose a modular device, comprising a motor, moveably disposed on a guidewire. However, Ritcher does not specifically disclose the movement between the two components as activated by gears.

Kindlein, as shown in Figure 6, discloses a moveable needle advanced and retracted within a housing due to moveable and interacting wheels. Although not specifically shown, it would have been obvious for the wheels to comprise threaded gears for more accurate movement. Ziegler et al. (hereinafter Ziegler) also shows movement between threaded gears to advance an object (Figures 1 and 5).

Additionally, Ritcher discloses an electric motor to move the catheter. Merely replacing the electric motor with a mechanical action simplifies the device and allows it to safely enter a patient. Since a drive mechanism utilizing gears to move an object along a track is well known in the art, as taught by Kindlein and Ziegler, it would have been obvious to

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one of ordinary skill in the art at the time of the invention for the drive mechanism of Ritcher to be simplified into a gear mechanism.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter (EP 0,976,417 A1) view of Kindlein (US 7,229,401 B2) or Ziegler et al. (US 6,971,990 B2).

Ritcher, as discussed in paragraph 3 and incorporated here by reference, discloses a modular device driven by a drive mechanism over a guide track. The drive mechanism comprises a motor that engages the guide track to advance the modular device along the guide track.

Ritcher does not specifically disclose the drive mechanism as a threaded member that rotationally engages the guide track. Kindlein, as shown in Figure 6, discloses a moveable needle advanced and retracted within a housing due to moveable and interacting wheels. Although not specifically shown, it would have been obvious for the wheels to comprise threaded gears for more accurate movement. Ziegler et al. (hereinafter Ziegler) also shows rotational movement between threaded gears to advance an object (Figures 1 and 5). Additionally, Ritcher discloses an electric motor to move the modular device. Merely replacing the electric motor with a mechanical action simplifies the device and allows it to safely enter a patient. Since a drive mechanism utilizing gears to move an object along a track is well known in the art, as taught by Kindlein and Ziegler, it would have been obvious to one of ordinary skill in the art at the

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time of the invention for the drive mechanism of Ritcher to be simplified into a threaded gear mechanism.

6. Claims 22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritcher (EP 0,976,417) in view of McAllister et al. (US 2002/0065523) and Cohen (US 5,167,239).

With regard to claim 22, Ritcher, as discussed in paragraph 3 and incorporated here by reference, discloses a modular device driven by a drive mechanism over a guide track. The modular device comprises an expandable balloon. The drive mechanism comprises a motor that engages the guide track to advance the modular device along the guide track.

Ritcher does not specifically disclose the modular device used for resecting tissue or an anchoring module.

McAllister discloses a modular device (1) that moves along a guidewire (3) to the desired location ([0029]). At this point, a window (20) on the modular device draws in tissue and then severs the tissue ([0030]; [0033]; Figure 3C). Therefore, McAllister teaches a modular device that resects tissue. It would have been obvious at the time of the invention for the modular device of Ritcher to comprise a tissue resection device, as disclosed by McAllister, which would crawl along a guidewire. This would be a convenient manner in which to guide the tissue resection modular device into position without causing it to buckle which can occur during pushing.

Although Ritcher does not specifically disclose the guidewire comprising an anchoring module, Cohen discloses a guidewire with a distal anchoring balloon (Figure 1). A balloon (14) located on the distal end of the balloon is inflated to anchor and secure the guidewire at the desired location within a patient's lumen (column 3, lines 29-36).

However, Cohen does not specifically disclose a motor to advance the anchoring balloon along the guidewire. Since Ritcher discloses a method of moving components along a guidewire in an easy and efficient crawl method, it would have been obvious at the time of the invention for the anchoring balloon to also comprise a module that can crawl along the guidewire to the distal location. This would allow the anchoring balloon to be advanced to the desired position after the guidewire is in place, which reduces trauma to the patient rather than advancing the balloon and guidewire simultaneously.

Therefore, Ritcher in view of McAllister and Cohen discloses a method of resecting tissue wherein an anchoring balloon module is advanced over a guidewire to the desired location and then expanded to secure the guidewire in place. A tissue resecting modular device is then advanced over the guidewire. The device then resects tissue and is then retracted proximally.

With regard to claim 24, when the anchoring balloon is expanded, the anchoring module is extended to thereby anchor the guide track.

With regard to claim 25, member (50) of McAllister attaches and grasps onto the tissue (Figure 3C). Therefore, before the tissue is completely cut, member (50)

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overlaps the claimed positioning device since it holds onto the tissue and therefore maintains the modular device in a certain position.

Response to Arguments

7. Applicant's arguments filed 05/27/2009 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that the sleeve (12) of Ackerman does not move the balloon along the catheter since the balloon is sealing affixed to the catheter, the balloon only changes shape, and at most the balloon moves in a direction perpendicular to the catheter.

With respect to argument (A), the fact that the balloon is fixed to the catheter is not found persuasive. The fluid is still displaced within the balloon causing at least a portion of the balloon to move with the sleeve. Ackerman specifically teaches that the fluid is displaced to inflate or deflate the balloon (column 4, lines 1-8). Additionally, Figures 5 and 6 show at least the top portion of the balloon moving along the catheter. Since the balloon is able to change shape and inflate with movement of the sleeve, this causes the balloon to therefore move along the catheter. Even a slight movement of only the top portion of the catheter is movement along the catheter. The whole balloon need not slide along the catheter to overlap the claims. Therefore, the balloon may change shape when inflated, but this change in shape causes movement along the catheter. Finally, the balloon does not just move in a direction perpendicular to the

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catheter as shown in Figure 6. Instead, at least a portion of the balloon moves in a direction parallel to the catheter longitudinal axis in order to inflate the balloon.

Specifically, applicant argues (B) that neither Kindlein nor Zeigler disclose a threaded hole.

With respect to argument (B), as discussed above, Figures 1 and 5 of Zeigler show a threaded member having a threaded hole. Specifically, roller (534) in Figure 5 comprises a threaded member and therefore forms a threaded hole. Although Kindlein shows wheels interacting for rotational movement and does not show the wheels as threaded, such are well known in the art. Threaded wheels would allow for more accurate rotational movement.

Specifically, applicant argues (C) that Ritcher is not relevant to devices such as anchoring balloons that are intended to remain permanently affixed at a particular location.

With respect to argument (C), however, the balloon (14) disclosed by Cohen is not intended to remain permanently within a patient's body. Cohen specifically teaches inserting the balloon and then removing it after the procedure is finished (column 13, lines 24-34; column 14, lines 11-16). Additionally, Ritcher broadly teaches moving a device along a guidewire to a target location ([0001]). Therefore, the balloon device of Cohen is applicable to the teachings of Ritcher.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

09/30/2009

/Amy T Lang/

Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

9/30/09